REMARKS

I. Status of the Claims

Claims 2-6, 8-13, 17, 18, and 23-26 were examined and rejected by the Office. Claims 5, 6, and 9 have been amended and claims 17-18 have been canceled. The amendments to the claims are supported by the specification and do not add new matter. Support for the amendment to claim 5 may be found in published paragraph [0116]. Support for the amendment to claim 6 may be found in published paragraph [0116], Example 1, and Example 2. The amendment to claim 9 was for clarity. New claim 102 has also been added. Support for claim 102 may be found in published paragraph [125]. The Applicants respectfully request the Examiner to consider the following remarks in light of the presently pending claims, 2-6, 8-10, and 23-26.

II. Specification Objections

Amendments to the specification have been made to correctly denote and define trademarks or trade names (see amended paragraphs 0162, 0164, 0173, 0177, 0211, and 0215). The specification was also amended to add degree symbols (see amended paragraphs 0089, 0129, 0137, and 0138). Amendments to the specification were also made to correct spelling errors (see amended paragraphs 0088, 0092, 0109, 0176, and 0177). In light of the above-cited amendments, the Applicants respectfully request withdrawal of all objections to the specification

III. 35 U.S.C. § 112, Second Paragraph, Rejections

(a) Pending claim 9 is definite

Reconsideration is respectfully requested of the rejection of claim 9 under 35 UCS § 112, second paragraph. The Office asserts that the term "relative proportions" is unclear. Since claim 9 depends from claim 6, in which the term "slurry" was defined, the superfluous words "manure and water in relative proportions of" were removed from the claim. The Applicants submit that amended claim 9 satisfies the requirements of 35 UCS § 112, second paragraph.

(b) Pending claims 5 and 6 are definite

Reconsideration is respectfully requested of the rejection of claims 5 and 6 under 35 UCS § 112, second paragraph. The Office asserts that the term "centrifugal-based separation" is unclear. This term was defined in the specification. Published paragraph [0116] states: "As used herein, centrifugal-based separation includes processing in either a mechanical rotated centrifugation or a static hydrocyclone." Claim 5 states that the "solid/liquid phase centrifugal-based separation" was by means of a hydrocyclone. Thus, claim 5 has been amended to clearly state that the separation means is via a hydrocyclone. In claim 6, the step (i.e., step 3) that recites the term "centrifugal-based separation" may be accomplished with either a centrifuge (see Example 1) or a hydrocyclone (see Example 2). Thus, claim 6 has been amended to remove the ambiguous term and clearly state that either method of separation may be used. In contrast, step 5 of claim 6 requires centrifugation, and step 7 of claim 6 requires use of a hydrocyclone. Removal of the term "centrifugal-based separation" from claim 6 rendered claims 17 and 18 redundant, and, thus, these claims were canceled. In light of the foregoing, it is respectfully submitted that pending claims 5 and 6 satisfy the requirements of 35 UCS § 112, second paragraph.

IV. 35 U.S.C. § 103 Rejections

(a) Pending claims 2-6, 8-10, and 23-26 are not rendered obvious by Conkle et al. in view of Singh et al.

Reconsideration is requested of the rejection of claims 2-6, 8-10, and 23-26 under 35 U.S.C. 103 (a) in view of Conkle et al. and Singh at al.[1]

Three criteria must be present to establish a *prima facie* case of obviousness.[2] First, the prior art reference must teach or suggest all the claim limitations. Second, there must be some suggestion or motivation in the knowledge generally available to one of ordinary skill in the art to modify the reference. Third, there must be a

[1] Conkle et al., WO 2000/50072; Singh et al. (1995) Cereal Chemistry 72(4):344-348.

[2] MPEP §2143.

reasonable expectation of success.[3] Not one of these three criteria is satisfied by Conkle et al. and/or Singh et al.-irrespective of whether the references are considered singly or taken together.

Claims 2-6, 8-10, and 23-26 each require use of a hydrocyclone to separate oocysts from a liquid suspension.

Conkle et al. disclose a method for separating and isolating oocysts from *Eimeria* (i.e., encysted protozoa) that uses a centrifuge to separate the oocysts from liquid suspensions. Nowhere do Conkle et al. disclose or suggest that a hydrocyclone could be used in their separation and isolation method. Singh et al. use a hydrocyclone to separate **starch particles** from protein particles in a solution of wet-milled corn. Nowhere do Singh et al. disclose or suggest that a hydrocyclone could be successfully used to separate and/or isolate **viable** oocysts from liquid suspensions. Moreover, the cited art does not provide the requisite motivation or reasonable expectation of success to modify the process for separating and/or isolating oocysts disclosed by Conkle et al. by substituting a hydrocyclone (as disclosed in Singh et al.) for a centrifuge.

In fact, if anything, the prior art **teaches away** from use of a hydrocyclone to separate living cells from aqueous cell suspensions. A *prima facie* case of obviousness may be rebutted by showing that the prior art, in any material way, teaches away from the claimed invention.[4] The prevailing view at the time the invention was filed, in fact, was that it was not possible to separate living cells from aqueous cell suspensions using a hydrocyclone. For example, U.S. Patent No. 5,547,858 specifically dictates:

> ...A liquid cyclone is well known as a wet type classifying machine which gives a centrifugal force in a fixed cylinder by rotating liquid and has been widely used for recovery of finely ground matter in a mine, removal of sand grains from pulp, classification of various starches, etc. These are all due to application of the function of a liquid cyclone to classify particles having a diameter larger than the critical diameter into the downstream side. In this case, however, a liquid cyclone fails to classify particles having a diameter smaller than the critical diameter and these particles are merely classified by a ratio of liquid volume at the upstream to that at the downstream. This concept is conventionally applied to crystal slurry of

[3] *Id.*

[4] *In re Geisler*, 116 F.3d 1465, 1471; 43 USPQ2d 1362, 1366 (Fed. Cir. 1997).

> a solution containing crystals to be concentrated using a liquid cyclone. But, when a solution containing cells is fed to the liquid cyclone, the cells have a diameter, smaller than the critical diameter so that there is no difference in concentration between the upstream and the downstream of the liquid cyclone, ***which makes separation of the cells impossible***.[5]

It was also believed at the time the present application was filed that viable organisms could not be separated using a hydrocyclone. For example, in the current application Applicants state, "the use of a hydrocyclone, not known to be used for living organisms, was previously ***believed to fatally damage the oocysts*** due to intense sheer forces [produced by the hydrocyclone during separation]."[6]

Because the disclosure of Conkle et al. and Singh et al., when taken singly or combined, do not teach or suggest all of the presently pending claim limitations, do not provide some suggestion or motivation to modify the reference teaching, and do not provide a reasonable expectation of success if the references were combined, a *prima facie* case of obviousness **has not been established**. In fact, as shown above, the prior art, which discloses that use of a hydrocyclones to separate cells is "impossible," teaches away from the invention defined by claims 2-6, 8-10, and 23-26. Accordingly, a skilled artisan empowered with the prior art cannot be deemed fairly motivated to modify the process for separating and/or isolating oocysts disclosed by Conkle et al. by substituting a hydrocyclone (as disclosed in Singh et al.) for a centrifuge. As stated in MPEP § 2143, where there is no motivation to modify a reference as proposed, the proposed modification is not obvious.

The Office, however, asserts that it would have been obvious at the time of the invention to modify the separation and isolation procedures as taught by Conkle et al. to use a hydrocyclone because Singh et al. taught that separation processes using a hydrocyclone "increased the yield of product, reduced the time required for separation, and eliminated the requirement of a large floor area."[7] This is not correct.

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[5] U.S. Patent Application No. 5,547,858, column 1, at lines 31 to 49 (emphasis added).

[6] U.S. Application Serial No. 10/799,083, at paragraph 122.

[7] Office Action dated 4/11/2007, at p. 7.

Singh et al. compared the use of a hydrocyclone to separate **starch** from wet-milled corn with the traditional starch tabling procedure (i.e., the use of long (~20 feet) sloped tables that allow starch granules to settle by gravity such that they can be separated from the liquid phase). While the advantages cited by Singh et al. are significant for the different methods used to separate starch from wet milled corn, they are not particularly relevant to the methods used to separate oocysts from a liquid suspension, as required by the method of claims 2-6, 8-10, and 23-26. For example, the amount of floor space needed for a hydrocyclone versus starch tables is very significant, while the amount of floor space used by a hydrocyclone or a centrifuge is not. Thus, none of the Office's alleged advantages cited for using a hydrocyclone to separate starch from wet-milled corn would have suggested or motivated one skilled in the art of protozoan oocyst isolation to use a hydrocyclone to separate oocysts from a liquid suspension. Considered collectively, as such, the combined teaching of the references are actually away from the Office's proposed substitution.

The Office also asserts that it would be expected-absent evidence to the contrary-to use a hydrocyclone to separate encysted protozoa from samples "effectively."[8] Applicants have submitted such evidence to the contrary. As detailed above, the prevailing view at the time the invention was filed was that it was not possible to separate living cells from aqueous cell suspensions using a hydrocyclone. In addition, hydrocyclones had not been used to separate living organisms because it was thought the sheer forces would damage the organisms. Thus, the knowledge available to those of skill at the time of the invention was either (1) that a hydrocyclone physically could not separate living organisms; or (2) if the hydrocyclone could separate living organisms-it would not be successful because the oocysts would be damaged and not be able to sporulate.

Because the references relied on by the Office and other prior art that existed when the present application was filed do not disclose or suggest the presently claimed method for separating and/or isolating oocysts using a hydrocyclone, the Office appears to be applying "hindsight reconstruction" by using the teaching of the Applicants' patent

[8] Office Action dated 4/11/2007, at p. 7

application as a guide for searching, and analyzing the references in the right way to arrive at the claims at issue.[9] Such hindsight reconstruction is clearly contrary to the law.[10] The Office has simply not set-forth any sufficient art-based rationale as to why a person of skill in the art would have been motivated to modify the separation and isolation procedures as taught by Conkle et al. to use a hydrocyclone as taught by Singh et al. Without this demonstration of the requisite motivation to make the Office's proposed modification, a *prima facie* case of obvious has not been established.

In view of the foregoing, the Applicants respectfully request withdrawal of the obviousness rejections of pending claims 2-6, 8-10, and 23-26 under Conkle et al. in view of Singh et al.

(b) Rejection of claims 11-13 under U.S.C. 103(a)

Reconsideration is requested of the rejection of claims 11-13 under 35 U.S.C. 103 (a) in view of Conkle et al., Singh at al, and in further view of Sjoerdsma et al.[11]

Claims 11-13 each require use of a hydrocyclone to separate oocysts. For all of the reasons detailed in section IV(a), use of a hydrocyclone to separate oocysts as required by claims 11-13 is not obvious in view of the cited art.

The defect in the Office's obviousness rejection is not cured by resort to Sjoerdsma et al. This reference does not disclose or suggest use of a hydrocyclone to separate oocysts. Instead, the reference discloses that mesh screens can be used to extract debris from biological matters.

In view of the foregoing, the Applicants respectfully request withdrawal of the obviousness rejections of pending claims 11-13 under Conkle et al. in view of Singh et al. in further view of Sjoerdsma et al.

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[9] See *Orthopedic Equipment Co. v. United States*, 217 U.S.P.Q 193 (Fed. Cir. 1983).

[10] See *In re Dow Chemical*, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988).

[11] Conkle et al., WO 2000/50072; Singh et al. (1995) Cereal Chemistry 72(4):344-348.

V. Conclusions

In light of the foregoing, the Applicants request entry of amendments to the specification and claims, withdrawal of the specification objections and claim rejections, and solicit an allowance of all pending claims, i.e., claims 2-6, 8-10, and 23-26.

The Commissioner is hereby authorized to change any and all fees that may be required or credit any overpayment to Deposit Account No. 50-1662.

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Respectfully Submitted,

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